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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bot *et al.*
Serial No. : 09/801,540 Examiner: To Be Assigned
Filed : March 8, 2001 Group Art Unit: 1632
For : IMMUNIZATION OF INFANTS

INFORMATION DISCLOSURE STATEMENT

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42,328
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January 29, 2003
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Sir:

In accordance with 37 C.F.R. § 1.56, Applicants respectfully request that the references relating to the above-mentioned application listed herein in reverse chronological order be made of record in the U.S. Patent and Trademark Office.

1. United States Patent No. 6,204,250, by Bot *et al.*, filed November 22, 1996, issued March 20, 2001.

2. United States Patent No. 5,969,109, United States Patent Application Serial No. 08/363,276, by Bona *et al.*, filed December 22, 1994, issued October 19, 1999.
3. *Bot *et al.*, 1999, "Induction of antibody response by DNA immunization of newborn baboons against influenza virus." *Viral Immunol* 12:91-6.
4. *Bot *et al.*, 1997, "Induction of humoral and cellular immunity against influenza by immunization of newborn mice with a plasmid bearing a hemagglutinin gene", *International Immunology*, Vol. 9, No. 11, pp.101-111.
5. *Bot *et al.*, 1997, "Immune Response of Neonates Elicited by Somatic Transgene Vaccination with Naked DNA", *Frontiers in Bioscience* 2, d173-188.
6. United States Patent No. 5,580,859, by Fegner *et al.*, issued December 3, 1996.
7. United States Patent No. 5,589,466, by Fegner *et al.*, issued December 31, 1996.
8. Verma *et al.*, Sept . 1997, "Gene Therapy-Promises, Problems, and Prospects," *Nature*, vol. 389: 239-242.
9. *Bot *et al.*, 1996, "Cellular Mechanisms Involved in Protection and Recovery from Influenza Virus Infection in Immunodeficient Mice", *J. Virol.* 70: 5668-5672.

10. *Bot *et al.*, 1996, "DNA Immunization of Newborn Mice with a Plasmid-Expressing Nucleoprotein of Influenza Virus", *Viral Immunology* Vol. 9, No. 4, pp.207-210.
11. Bot *et al.*, 1996, "Kinetics of generation and persistence on membrane class II molecules of a viral peptide expressed on foreign and self proteins." *J Immunol.* 157:3436-42.
12. Forsthuber *et al.*, 1996, "Induction of T_H1 and T_H2 Immunity in Neonatal Mice", *Science* 271: 1728-1730.
13. Mor *et al.*, 1996, "Induction of Neonatal Tolerance by Plasmid DNA Vaccination of Mice", *J. Clin. Invest.* 98: 2700-2705.
14. Ridge *et al.*, 1996, "Neonatal Tolerance Revisted: Turning on Newborn T Cells with Dendritic Cells", *Science* 271: 1723-1725.
15. Sarzotti *et al.*, 1996, "Induction of Protective CTL Responses in Newborn Mice by a Murine Retrovirus", *Science* 271: 1726-1728.
16. Crowe, 1995, "Current approaches to the development of vaccines against disease caused by respiratory syncytial virus (RSV) and parainfluenza virus (PIV)", *Vaccine* 13: 415-421.
17. Davis *et al.*, 1995, "DNA-based immunization", *Molecular and Cell Biology of Human Disease Series*, 5: 368-387.

18. Donnelly *et al.*, 1995, "Preclinical efficacy of a prototype DNA vaccine: Enhanced protection against antigenic drift in influenza virus", *Nature Med.* 1: 583-587.
19. Justewicz *et al.*, 1995, "Antibody-Forming Cell Response to Virus Challenge in Mice Immunized with DNA Encoding the Influenza Virus Hemagglutinin", *J. Virol.* 19: 7712-7717.
20. Marshall, E. August 1995, "Gene Therapy's Growing Pains," *Science*, 269: 1050-1055.
21. Martins *et al.*, 1995, "DNA Vaccination against Persistent Viral Infection", *J. Virol.* 69: 2574-2582.
22. Orkin *et al.* Dec. 1995 "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," NIH Report and Recommendation.
23. Stedman's Medical Dictionary, 1995, 26th Edition., "pathogen" p.1312, Spraycar, M., Ed., Williams & Wilkins, publ.
24. International Application No. PCT/US94/02751, by Merck & Co. and Vical, Inc, Donnelly *et al.*, inventors, published Sept. 29, 1994. as WO 94/21797.
25. Bachmann *et al.*, 1994, "In vivo versus in vitro assays for assessment of T- and B- cell function" *Current Opinion in Immunology*, 6:320-326.*

26. Donnelly *et al.*, 1994, "Immunization with DNA", *J. Immunol. Meth.* 176: 145-152.
27. Isobe *et al.*, 1994, "Intact antiinfluenza virus immune response in targeted kappa-deficient mice," *Viral Immunol.* 7:25-301.
28. Katsumi *et al.*, 1994, "Humoral and Cellular Immunity to an Encoded Protein Induced by Direct DNA Injection", *Human Gene Therapy* 5: 1335-1339.
29. Ozaki *et al.*, 1994, "Investigation of Varicella-Zoster Virus DNA by the Polymerase Chain Reaction in Healthy Children With Varicella Vaccination", *J. med. Virol.* 42: 47-51.
30. Rossiter *et al.*, 1994, "Processing of viable group A streptococci leads to major histocompatibility complex class II presentation of T cell epitopes from the major protective antigen," *Eur. J. Immunol.* 24:1244-1247.
31. Vordermeier *et al.*, 1994, "Promiscuous T cell recognition of an H-2 IA-presented mycobacterial epitope," *Eur. J. Immunol.* 24:2061-2067.
32. Assateerawatt *et al.* 1993, "Immunogenicity and efficacy of a recombinant DNA hepatitis B vaccine, GenHevac B Pasteur in high risk neonates, school children and healthy adults," *Asia Pacific Journal of Allergy and Immunology.* vol. 11: 85-91.
33. Lai *et al.* 1993, "Five-year follow-up of a prospective randomized

trial of hepatitis B recombinant DNA yeast vaccine vs plasma-derived vaccine in children: immunogenicity and anamnestic responses," *Hepatology*, vol. 18: 763-767.

34. del Canho *et al.* 1993, "Immunogenicity of 20 micrograms of recombinant DNA hepatitis B vaccines in healthy neonates: a comparison of three different vaccination schemes," vol. 41: 30-34.

35. Doherty, 1993, "Hepatitis viruses and protection against infection in children", *Current Opin. Pediatrics* 5: 3-13.

36. Fynan *et al.*, 1993, "DNA vaccines: Protective immunizations by parenteral, mucosal, and gene-gun inoculations", *Proc. Natl. Acad. Sci USA* 90: 11478-11483.

37. Montgomery *et al.*, 1993, "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors", *DNA and Cell Biol.* 12: 777-783.

38. Mulligan, R.C. 1993, "The Basic Science of Gene Therapy," *Science*, vol. 260: 926-932.

39. Ulmer *et al.*, 1993, "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein", *Science* 259:1745-1748.

40. Kuzu *et al.*, 1993, "In vivo priming effect during various stages of ontogeny of an influenza A virus nucleoprotein peptide", *Eur. J. Immunol.* 23:1397-1400.

41. De Magistris, 1992, "Antigen analog-major histocompatibility complexes act as antagonists of the T cell receptor," *Cell* 68:625-634.
42. Li *et al.*, 1992, "Influenza A virus transfectants with chimeric hemagglutinins containing epitopes from different subtypes," *J. Virol.* 66:399-404.
43. Nelson *et al.*, 1992, "Identification of the naturally processed form of hen egg white lysozyme bound to the murine major histocompatibility complex class II molecule I-Ak," *Proc. Natl. Acad. Sci. U.S.A.* 89:7380-7383.
44. Partidos *et al.*, 1992, "The influence of orientation and number of copies of T and B cell epitopes on the specificity and affinity of antibodies induced by chimeric peptides," *Eur. J. Immunol.* 22:2675-2680.
45. Zaghouani *et al.*, 1992, "Cells expressing an H chain Ig gene carrying a viral T cell epitope are lysed by specific cytolytic T cells," *J. Immunol.* 148:3604-3609.
46. Leclerc *et al.*, 1991, "The cellular location of a foreign B cell epitope expressed by recombinant bacteria determines its T cell-independent or T cell-dependent characteristics," *J. Immunol.* 147:3545-3552.
47. International Application No. PCT/US90/01515, by Vical, Inc., and Wisconsin Alumni Research Foundation, Fegner *et al.*, inventors, published Oct. 4, 1990, as WO 90/11092.

48. Ho *et al.*, 1990, "Identification of two promiscuous T cell epitopes from tetanus toxin," *Eur. J. Immunol.* 20:477-483.
49. Benjamini and Leskowitz, 1988, "Immunology, A Short Course", Alan R. Liss, Inc., New York, p. 65.
50. Taylor *et al.*, 1987, "Class I MHC molecules rather than other mouse genes dictate influenza epitope recognition by cytotoxic T cells," *Immunogenetics* 26:267-272.
51. Clarke *et al.* 1987," Improved immunogenicity of a peptide epitope after fusion to hepatitis B core protein," *Nature* 330:381-384.
52. Lai *et al.*, 1986,"Use of the hepatitis B recombinant DNA yeast vaccine (H-B-Vax II) in children: two doses vs three doses of 5 micrograms regime; an interim report," *J. of Infection*, vol. 13, Suppl. A: 19-25.
53. Taylor *et al.*, 1986, "Influenza nucleoprotein-specific cytotoxic T-cell clones are protective *in vivo*", *Immunol.* 58:417-420.
54. Caton *et al.* 1982," The antigenic structure of the influenza virus A/PR/8/34 hemagglutinin (H1 subtype)," *Cell* 31:417-427.
55. Rubinstein *et al.*, 1982, "Idiotypic-Anti-Idiotypic Network", *J. Exp. Med.* 156:506-521.
56. Townsend and Skehel. 1982, "Influenza A specific cytotoxic T-cell

clones that do not recognize viral glycoproteins," *Nature* 300:655-657.

57. Kilbourne, 1976, "Comparative efficacy of neuraminidase-specific and conventional influenza virus vaccines in induction of antibody to neuraminidase in humans," *J. Infect. Dis.* 134:384-394.

58. Zinhermagel and Doherty. 1974, "Restriction of *in vitro* Tcell-mediated cytotoxicity in lymphocytic choriomeningitis within in a syngeneic or semiallogeneic system," *Nature* 248:701-702.

59. Billingham, 1956, "Quantitative studies on tissue transplantation immunity - III. Actively acquired tolerance," *Proc. R. Soc. London Ser. B.* 239:44:359-412.

60. Billingham *et al.*, 1953, "Actively acquired tolerance of foreign cells," *Nature* 172:603-606.

61. Owen, 1945, "Immunogenetic consequences of vascular anastomoses between bovine twins," *Science* 102:400-401.

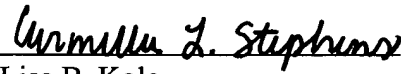
The referenced citations are listed in the accompanying PTO Form 1449 and copies of the references are provided. The Examiner's attention is particularly invited to references marked with an asterisk, which are deemed to be particularly relevant.

Identification of the above-listed references is not to be construed as an admission of the Applicants or the attorneys of the Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the above-mentioned application.

Applicants believe that no fee is required with the submission of this Information Disclosure Statement. However, if any fee is due, or if any overpayment has been made, in connection with the filing of this response, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 02-4377. Duplicate copies of this page is enclosed.

Respectfully submitted,


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